

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENERGAID powder for oral solution for calves.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active Substance:

Each 165 g sachet contains:

|                             |       |   |
|-----------------------------|-------|---|
| Sodium citrate dihydrate    | 9.73  | g |
| Sodium acetate anhydrous    | 5.41  | g |
| Sodium propionate anhydrous | 1.91  | g |
| Sodium chloride             | 4.65  | g |
| Potassium chloride          | 2.96  | g |
| Glucose anhydrous           | 135.3 | g |

On reconstitution in 2 litres of water the available ion concentrations are as follows:

|            |              |
|------------|--------------|
| Sodium     | 133 mmol/l   |
| Potassium  | 20 mmol/l    |
| Chloride   | 60 mmol/l    |
| Propionate | 10 mmol/l    |
| Acetate    | 33 mmol/l    |
| Citrate    | 16.54 mmol/l |
| Dextrose   | 375 mmol/l   |

The propionate, acetate and citrate ions together yield 93 mmol/l bicarbonate.

#### Excipients:

|                             |      |   |
|-----------------------------|------|---|
| Sunset Yellow Dye (E110)    | 0.1  | g |
| Silica, colloidal anhydrous | 4.97 | g |

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Powder for oral solution.

A pink powder

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Calves

### **4.2 Indications for use, specifying the target species**

The veterinary medicinal product is a calorific oral rehydration product indicated for the reversal of the processes of dehydration, electrolyte loss, metabolic acidosis and weight loss associated with scour in calves. Efficacy has been demonstrated in *E. coli* infected calves.

### **4.3 Contraindications**

None.

### **4.4 Special Warnings for each target species**

Milk or milk replacer may continue to be administered at the onset of the veterinary medicinal product administration if deemed appropriate by a veterinary surgeon.

In severe cases some calves may require additional intravenous therapy. In such cases consult a veterinary surgeon.

If signs of disease persist or appear the veterinary surgeon or veterinary practitioner should re-evaluate the situation.

A nipple bottle or tube feeder may be used if considered appropriate. On reconstitution the silicon dioxide does not go into solution but remains as a fine powder in the mixing vessel.

### **4.5 Special precautions for use**

#### **Special precautions for use in animals**

None.

#### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

None

### **4.6 Adverse reactions (frequency and seriousness)**

None

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Not investigated.

#### **4.9 Amounts to be administered and administration route**

*Dosage:* A solution for oral administration, is prepared as follows: dissolve the contents of one sachet in 2 litres of clean, warm water. Keep feeding utensils clean.

*Administration:* Two litres of the solution, freshly prepared as directed, is offered twice daily for 2 days. For the next two days, 1 litre of solution and 1 litre of milk or milk replacer (either mixed together or fed separately) are administered morning and evening. Thereafter normal diet is resumed. If symptoms are severe, the solution may be fed 3 or 4 times daily. The solution may be given for a maximum of 4 days only, when administered on its own. Normal feeding should be resumed after the course of treatment.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

The product has been demonstrated to be well tolerated in the target species. Given the osmotic character of the product, overdose may lead in some cases to softening of the faeces. Therefore, care should be taken in the correct preparation of the resulting oral rehydration solution.

#### **4.11 Withdrawal period**

Zero days

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Oral electrolytes and carbohydrates

**ATC Vet Code:** QA07CQ02

#### **5.1 Pharmacodynamic properties**

The product provides an adequate source of nutrients and electrolytes to correct the symptoms associated with diarrhoea. In particular, it provides potassium to counteract decreasing intracellular potassium levels.

The intestinal absorption of water is dependant largely on sodium absorption. The concentration of sodium at a level of 133 mmol/l optimises the basic rehydrating ability of the product. Certain compounds including glucose and the bicarbonate precursors, citrate, propionate and acetate are able to assist enteric sodium uptake.

Absorption and metabolism of the bicarbonate precursors provides a potential 93 mmol/l of bicarbonate which has an important role to play in correcting acidosis, and terminally are an additional source of energy for the weakened calf. The final reconstituted solution also provides 375 mmol/l of glucose providing a high calorific content. Glucose, citrate and propionate all enter the Tricarboxylic Acid (Krebs) Cycle leading to the formation of energy, whilst acetate although utilised by a different route still yields energy.

## **5.2 Pharmacokinetic properties**

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## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sunset Yellow Dye (E110)  
Silica, colloidal anhydrous

### **6.2 Incompatibilities**

None.

### **6.3 Shelf life**

Unopened sachets: 24 months

Reconstituted solution: 24 hours.

### **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in a dry place.

### **6.5 Nature and composition of immediate packaging**

Each sachet contains 165 g and is composed of paper/low density polyethylene/aluminium. 24 sachets are contained in each carton.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused product or waste material should be disposed of in accordance with national requirements.

**7.     MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited  
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Camlough Road  
NEWRY  
Co. Down, BT35 6JP  
Northern Ireland

**8.     MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4127

**9.     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

18th September 2002

**10.    DATE OF REVISION OF THE TEXT**

July 2007

**PROHIBITION OF SALE, SUPPLY AND/OR USE**